Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HIROAKI OKUSHIN

Appeal No. 2002-1728
Application No. 09/339,239

HEARD: January 21, 2003

Before WINTERS, METZ, and ADAMS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 18 through 23 and 25, which are all of the claims remaining in the application.

The Invention

The present invention relates to a therapeutic agent for persistent disappearance (persistent seronegative) of hepatitis B virus (HBV)-DNA in treating chronic hepatitis B. More specifically, the invention relates to a method for treating hepatitis B comprising administering a daily effective dose of β-interferon in a plurality of individual doses

which total the daily effective dose.

Claim 18, which is illustrative of the subject matter on appeal, reads as follows:

18. A method for the persistent negation of HBV-DNA or for inducing the seroconversion of HBe antigen to HBe antibody or for treating hepatitis B comprising administering a daily effective dose of interferon β (IFN-β) in a plurality of individual doses which total said daily effective dose.

The Prior Art References

In rejecting the appealed claims under 35 U.S.C. § 103(a), the examiner relies on the following prior art references:

Eisenberg et al. (Eisenberg), "Preliminary Trial of Recombinant Fibroblast Interferon in Chronic Hepatitis B Virus Infection," Antimicrobial Agents and Chemotherapy, Vol. 29, No. 1, pp. 122-126 (1986)

Chiang et al. (Chiang), "Pharmacokinetics and Antiviral Activity of Recombinant Human Interferon-β_{ser17} in African Green Monkeys," Journal of Interferon Research, Vol. 13, pp. 111-120 (1993)

Krogsgaard et al. (Krogsgaard), "Relation Between Treatment Efficacy and Cumulative Dose of Alpha Interferon in Chronic Hepatitis B," Journal of Hepatology, Vol. 25, pp. 795-802 (1996)

Park et al. (Park), "Effects of Low Dose, Short Term Recombinant α-Interferon Therapy in Patients with Chronic Hepatitis B," Gastroenterology, Vol. 110, No. 4, p. A1290 (1996)

The Rejection

Claims 18 through 23 and 25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Krogsgaard, Park, or Eisenberg, either of those "primary" references considered in view of Chiang.

Deliberations

Our deliberations in this matter have included evaluation and review of the

following materials: (1) the instant specification, including all of the claims on appeal; (2) applicant's Appeal Brief (Paper No. 15) and the Reply Brief (Paper No. 18); (3) the Examiner's Answer (Paper No. 16); and (4) the above-cited prior art references.

On consideration of the record, including the above-listed materials, we affirm the examiner's decision rejecting claim 18. However, we reverse the examiner's decision rejecting claims 19 through 23 and 25.

Discussion

In the Appeal Brief, applicant groups claims 18 and 19 together (Paper No. 15, section VII. Grouping of Claims). Applicant argues that these claims patentably distinguish over the combination of Eisenberg and Chiang in view of the following limitation in dependent claim 19: "wherein the daily effective dose is administered in two portions for four weeks." (Paper No. 15, page 19, first full paragraph). The argument is flawed, however, and amounts to a non-sequitur with respect to the patentability of claim 18 over the combined disclosures of Eisenberg and Chiang. This follows because the above-quoted limitation in claim 19 does not appear in claim 18. In other words, applicant's principal argument for the patentability of claim 18 over the combined disclosures of Eisenberg and Chiang relies on a limitation not in claim 18. Accordingly, the argument lacks merit.

Eisenberg discloses a method for treating hepatitis B by administering a daily effective dose of "a new-genetically engineered product," β_{ser} interferon. Applicant does not deny that Eisenberg discloses every feature of the subject matter sought to be

patented in claim 18 except administration "in a plurality of individual doses which total said daily effective dose." On this point, we agree with the examiner that it would have been obvious to modify the method of Eisenberg, per the teachings of Chiang, by administering β_{ser} interferon "in a plurality of individual doses which total said daily effective dose." More specifically, it would have been obvious to modify the method of Eisenberg, per the teachings of Chiang, by administering β_{ser} interferon twice daily. We are persuaded that a person having ordinary skill, armed with the disclosure of Chiang, would have found adequate reason, suggestion, or motivation to modify the method of Eisenberg by administering β_{ser} interferon twice daily; and would have arrived at the method recited in claim 18. We conclude, therefore, that claim 18 would have been prima facie obvious in view of the combined disclosures of Eisenberg and Chiang. On this record, applicant has not presented objective evidence of non-obviousness serving to rebut the prima facie case.

Applicant appears to acknowledge that a person having ordinary skill in the art would have been motivated to administer Eisenberg's β_{ser} interferon in twice daily dosages, per the teachings of Chiang. See the Appeal Brief, Paper No. 15, page 19, first full paragraph ("one of ordinary skill in the art combining the teachings of Eisenberg et al. and Chiang et al. would only be motivated to administer the IFN-β_{ser} of Eisenberg et al. in twice daily dosages for a period of time not exceeding ten days"). Again, applicant does not set forth any argument in the Appeal Brief, based on a limitation in claim 18, which would serve to patentably distinguish that claim over the combined disclosures of Eisenberg and Chiang.

The rejection of claim 18 under 35 U.S.C. § 103(a), to the extent predicated on

the combined disclosures of Eisenberg and Chiang, is affirmed.

Claims 19 through 23 and 25, however, stand on different footing.

Claim 19 depends from claim 18 and adds the further limitation "wherein the daily effective dose is administered in two portions for four weeks." Claim 20 also depends from claim 18 and adds the limitation "wherein the daily effective dosage of IFN-β is administered in a plurality of individual doses per day for a predetermined number of days, and subsequently administered in one portion per day." In our judgment, the cited prior art is insufficient to support a conclusion of obviousness of claims containing those limitations. On this record, the examiner has not established that the combination of Chiang with either Krogsgaard, Park, or Eisenberg would have led a person having ordinary skill to the specific methods recited in claims 19 and 20. As indicated, those claims require a specific regimen or protocol for treating hepatitis B.

Claims 21 and 22 depend from claim 19 and add further limitations. Likewise, claims 23 and 25 depend from "any one of claims 20 to 22," or 23, respectively, and also add further limitations. Again, the examiner has not established that the combination of Chiang with either Krogsgaard, Park, or Eisenberg would have led a person having ordinary skill to the specific methods recited in claims 21 through 23 and 25.

The rejection of claims 19 thorugh 23 and 25 under 35 U.S.C. § 103(a) as unpatentable over Krogsgaard, Park, or Eisenberg, either of those "primary" references considered in view of Chiang, is reversed.

Accordingly, the examiner's decision is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

Sherman D. Winters Administrative Patent Judge	)
Andrew H. Metz Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Donald E. Adams Administrative Patent Judge	)

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